K061507

KLS L.P.

SEP 21 2006

SonicWeld Rx Endobrow Fixation

510(k) Summary

Submitter:	KLS-Martin, L.P. 11239-1 St. Johns Industrial Parkway South Jacksonville, FL 32246 Phone: 904-641-7746 Fax: 904-641-7378
Contact Person:	Jennifer Damato Director RA/QA
Date of Summary:	19 May 2006
Device Name:	SonicWeld Rx Endobrow Fixation
Trade Name:	SonicWeld Rx Endobrow Fixation
Common Name:	Bone Plate
Classification Name and Number:	Bone plate (CFR 872.4760)
Regulatory Class:	II
Predicate Devices:	Resorb-X SF (K051236) The Bioplate Resorbable Endobrow Fixation System (K051845) LactoSorb Craniofacial Anchor-Push Screw (K013557)
Intended Use:	The SonicWeld Rx Endobrow Fixation will be used to support non-load bearing tissues of the craniofacial skeleton, including but not limited to endobrow fixation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2006

Ms. Jennifer Damato
Director RA/QA
KLS-Martin, L.P.
11239 St. Johns Industrial, Parkway South
Jacksonville, Florida 32246

Re: K061507
Trade/Device Name: SonicWeld Rx Endobrow Fixation
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: September 1, 2006
Received: September 6, 2006

Dear Ms. Damato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061507

Device Name: SonicWeld Rx Endobrow Fixation

Indications For Use:

The SonicWeld Rx Endobrow Fixation will be used to support non-load bearing tissues of the craniofacial skeleton, including but not limited to endobrow fixation.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]
...on Sign-Off)
...n of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...Number K061507